

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of claims:

1. (Withdrawn) A method for surgically attaching a ventricular assist device to the circulatory system of a living subject, said method comprising the steps of:

obtaining a ventricular assist device comprised of a housing for directing blood flow, a pump able to receive and convey blood, a first conduit of fixed dimensions and configuration having two open ends and at least one internal lumen for directing the flow of blood to said pump, a second conduit of fixed dimensions and configuration having two open ends and at least one internal lumen for conveying blood from said pump, and a source of power for the operation of said pump;

joining a linking connector to an end of said first conduit to form a prepared conduit for accessing and directing blood flow, said linking connector being of determined dimensions and configuration, being deformable on-demand, and being suitable for passage through an aperture;

acquiring a piercing introducer assembly suitable for the introduction of a prepared conduit to the vascular system of a living subject, said introducer assembly comprising:

a perforator instrument comprised of

(i) at least one elongated supporting shaft of predetermined overall dimensions and axial configuration,

(ii) a handle attached at one end to said supporting shaft; and

(iii) a perforating headpiece integrally joined to the other end of said supporting shaft, said perforating headpiece comprising a perforating tip, a penetrating body, and a base aspect, and

(iv) conduit controlling means disposed adjacent to said perforating headpiece on said supporting shaft of said perforator instrument;

attaching said linking connector of said prepared conduit to a chamber of the heart in the living subject using said piercing introducer assembly such that said linking connector of said prepared inflow conduit passes through an aperture in the heart and deforms within a chamber of the heart, thereby securing said conduit to the interior of heart chamber and placing said secured conduit in blood flow communication with the interior of the heart chamber;

surgically affixing said second conduit to the vascular system of the living subject through a surgical means; and

connecting an end of said secured conduit and an end of said surgically affixed conduit to said pump of said ventricular assist device.

2. (Withdrawn) The method as recited by claim 1 wherein said first conduit is an inflow conduit and said second conduit is an outflow conduit.

3. (Withdrawn) The method as recited by claim 1 wherein second conduit comprises a linking connector joined to one end of said conduit.

4. (Withdrawn) The method as recited in claim 1 wherein said heart chamber is the left ventricle of the heart and said blood vessel is the aorta.

5. (Withdrawn) The method as recited in claim 1 wherein said heart chamber is the right ventricle of the heart and said blood vessel is the pulmonary artery.

6. (Original) A method for surgically attaching a ventricular assist device to the circulatory system of a living subject, said method comprising the steps of:

obtaining a ventricular assist device comprised of a housing for directing blood flow, a pump able to receive and convey blood, an inflow conduit of fixed dimensions and configuration having two open ends and at least one internal lumen for directing the flow of blood to said pump, an outflow conduit of fixed dimensions and configuration having two open ends and at least one internal lumen for conveying blood from said

pump, and a source of power for the operation of said pump;

joining a linking connector to an end of said inflow conduit to form a prepared inflow conduit for accessing and directing blood flow, said linking connector being of determined dimensions and configuration, being deformable on-demand, and being suitable for passage through an aperture in and deformation within a first blood vessel, whereby said deformation serves to secure said prepared inflow conduit to a first blood vessel and places said secured inflow conduit in fluid flow communication with the interior of a first blood vessel;

joining a linking connector to an end of said outflow conduit to form a prepared outflow conduit for redirecting and conveying blood flow, said linking connector being of determined dimensions and configuration, being deformable on-demand, and being suitable for passage through an aperture in and deformation within a second blood vessel, whereby said deformation serves to secure said prepared outflow conduit to a second blood vessel and places said secured outflow conduit in fluid flow communication with the interior of a second blood vessel;

acquiring a catheterless, piercing introducer assembly suitable for the introduction and sutureless juncture of a prepared conduit to the vascular system of a living subject, said introducer assembly comprising:

a perforator instrument comprised of

(i) at least one elongated supporting shaft of predetermined overall dimensions and axial configuration,

(ii) a handle attached at one end to said supporting shaft; and

(iii) a perforating headpiece integrally joined to the other end of said supporting shaft, said perforating headpiece comprising a perforating tip, a penetrating body, and a base aspect, and

(iv) conduit controlling means disposed adjacent to said perforating headpiece on said supporting shaft of said perforator instrument;

attaching said linking connector of said prepared inflow conduit to a first blood vessel in the living subject using said piercing introducer assembly such that said linking connector of said prepared inflow conduit passes through an aperture in and deforms

within a first blood vessel, thereby securing said inflow conduit to the interior of the first blood vessel and placing said secured inflow conduit in blood flow communication with the interior of a first blood vessel;

affixing said linking connector of said prepared outflow conduit to a second blood vessel in the living subject using said piercing introducer assembly such that said linking connector of said prepared outflow conduit passes through an aperture in and deforms within said second blood vessel, thereby securing said outflow conduit to the interior of the second blood vessel and placing said secured outflow conduit in blood flow communication with the interior of the second blood vessel; and

connecting an end of said secured inflow conduit and an end of said secured outflow conduit to said pump of said ventricular assist device.

7. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said ventricular assist device is selected from the group consisting of the HeartMate ventricular assist device, the Thoratec assist device, the Novacor ventricular assist device, the MicroMed (DeBakey) device, the Arrow LionHeart device, and the Levitronics device.

8. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said perforator instrument of said piercing introducer assembly further comprises a volumetric shaft having two open ends and at least one sidewall of determinable dimensions, said sheath being (1) sized at one open end for on-demand placement adjacent to and aligned closure with said perforating headpiece of said perforator instrument, (2) substantially annular in configuration over its axial length, and (3) adapted for protective positioning around and volumetric spatial envelopment of at least a portion of said supporting shaft extending from said perforating headpiece of said perforator instrument, said sheath providing a protective covering for said enveloped spatial volume then surrounding said supporting shaft; and position holding means attachable to and detachable from said volumetric sheath and said supporting shaft of said perforator instrument for holding said volumetric sheath and the enveloped spatial volume at a set position around said

supporting shaft of said perforator instrument.

9. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said supporting shaft of said introducer assembly is hollow over at least a portion of its length.

10. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said conduit controlling means of said introducer assembly comprises an inflatable and deflatable on-demand balloon appliance disposed adjacent to said perforating headpiece.

11. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said linking connector joined to said conduit ~~is formed of~~ comprises a shape-memory alloy.

12. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said linking connector joined to said conduit ~~is formed of~~ comprises a super-elastic alloy.

13. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said linking connector ~~[[is]]~~ comprises a wire meshwork.

14. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said conduit comprises a tube formed of a synthetic material.

15. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said conduit further comprises a tube ~~formed of~~ comprising naturally occurring matter.

16. (Currently amended) The method as recited in claim [[1 or]] 6 wherein said conduit further comprises one or more valves.

17. (Currently amended) The method as recited in claim [[1 or]] 6 ~~which incorporates the use of~~ further comprising using a stabilizing ring to hold the conduit to the ~~heart or~~ vessel.

Applicant : Ducksoo Kim
Serial No. : 10/786,413
Filed : February 25, 2004
Page : 7 of 8

Attorney Docket No.: 40022-006001

18. (Currently amended) The method as recited in claim [[1 or]] 6 [[where]]
wherein the connection is sutureless.